Impact of Computer-Generated Personalized Goals on HbA_{1c}

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OBJECTIVE — The public is increasingly aware of the importance of HbA_{1c} testing, yet the vast majority of patients with diabetes do not know their HbA_{1c} status or goal. We set forth to evaluate the impact of a system that provides uniquely formatted and personalized reports of diabetes status and goals on changes in HbA_{1c} levels.

RESEARCH DESIGN AND METHODS — A total of 150 patients with diabetes were randomized to receive either standard care or intervention inclusive of a computer-generated 11" × 17" color poster depicting an individual's HbA_{1c} status and goals along with personalized steps to aid in goal achievement. All patients enrolled received diabetes education during the 3 months before enrollment. HbA_{1c} was performed at baseline and 6 months.

RESULTS — At baseline, there were no significant differences between patient groups in terms of age, sex, education level, race, and HbA_{1c} or lipid levels. Among patients with baseline $HbA_{1c} \geq 7.0\%$, there was an 8.6% (0.77% absolute) reduction in HbA_{1c} among control subjects compared with a 17.0% (1.69% absolute) decline in the intervention group ($P = 0.032$). There were no differences between the control and intervention groups with respect to the frequency of patients experiencing any decline in HbA_{1c} (63 vs. 69%, $P = 0.87$); among these patients experiencing a decline, the most substantial reductions were seen with the control group, which had a 13.3% (1.15% absolute) decline compared with the intervention patients, who reduced their HbA_{1c} by 24.2% (2.26% absolute reduction; $P = 0.0048$). At study close, 77% of the patients had their poster displayed on their refrigerator.

CONCLUSIONS — This unique and personalized computer-generated intervention resulted in HbA_{1c} lowering comparable to that of hypoglycemic agents.

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Written goals and objectives lay the foundation for achieving success in most disciplines, including business, science, and education. Written contracts between health educators and patients have resulted in improved outcomes by shifting the locus of control from the health care provider to the patient (1–3). These principles have not typically been incorporated into medical school curricula, nor are physicians exposed to innovative modes of communication that may aid patients in achieving their health goals. For example, people who know their health goals and believe that these goals are within their control are more likely to have improved outcomes and engage in self-care behaviors, including exercise and weight loss programs (1–15).

Despite the successful efforts of numerous national organizations in raising public awareness of the role of HbA_{1c} in the development of diabetes-related complications, most patients with the disease have never heard of the term HbA_{1c} and do not know their HbA_{1c} levels and target goal. Numerous studies underscore the opportunities missed by physicians for providing diabetes counseling aimed at optimizing glycemic control (8–18). For example, among large managed care organizations in which 92% of patients perform self blood glucose monitoring, less than one-third had heard of the "A-One-C" test (16,17).

Traditional diabetes self-management training programs have had limited efficacy on glycemic control when evaluated 6 months after the intervention (18–25). Conventional methods of communicating health messages to patients via brochures, videos, and booklets are also of limited value, and there are no standardized educational materials demonstrating efficacy in improving diabetes outcomes (26–28). Because physicians have less time to see more patients, and preventive services are almost nonexistent in most practices, creative solutions are required to address the realities of modern health care. We designed a computer program that produces unique, customized computer-generated tools that provide patients with their diabetes status, goals, and steps to meet these goals. We set forth to evaluate whether personalized and uniquely delivered laboratory results along with written goals might facilitate HbA_{1c} lowering.

RESEARCH DESIGN AND METHODS

— Identification and enrollment was initiated among 150 patients with diabetes completing an American Diabetes Association (ADA)-recognized diabetes education program during the 3-month period before study enrollment. All patients were enrolled between October 1998 and April 1999.

Exclusion criteria

Patients giving a history of renal insufficiency with a creatinine level >1.5 mg/dl, women who were pregnant at the time or planning a pregnancy during the study period, and patients using insulin pumps were excluded. Patients who could not read were excluded from the study. To avoid spurious HbA_{1c} results, patients

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Abbreviations: ADA, American Diabetes Association; CDE, certified diabetes educator.
A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Table 1—*Tools received by intervention group versus control subjects*

	Intervention		Standard care	
	Patient	Physician	Patient	Physician
Poster	√			
Wallet card	√			
Monthly postcards	√			
Color chart report		√		
Traditional lab report		√		√

who received a blood transfusion within the past 30 days and those with an underlying illness, such as malignancy or a condition that was expected to impact their survival over the next 6 months, were also excluded.

Protocol

All patients were told they were entering an educational study designed to evaluate the impact of diabetes educational tools on outcomes. Patients who met enrollment criteria and agreed to participate were asked to read and sign an informed consent document. A certified diabetes educator (CDE) obtained each patient's baseline demographic data, weight, and blood pressure level, as well as a list of current medications. Additionally, laboratory tests including HbA_{1c}, direct LDL cholesterol, HDL cholesterol, and spot urine for microalbumin were performed on all patients. Baseline HbA_{1c} level was not a study exclusion.

Each participant completed a brief patient questionnaire. It included the patient's report of diet, exercise, smoking habits, frequency of foot examinations, and the date of the most recent dilated eye examination. The questionnaire provided multiple options, and participants were asked to select the one best choice. Included was a question of whether or not patients had heard of the term "hemoglobin A1c" or the "A-One-C" blood test. All patients who were not aware of the test were told about the test and its importance in evaluating diabetes control.

After the initial interview, we randomly assigned patients to standard care or the experimental intervention. All baseline patient data and questionnaire responses were entered into a relational database and algorithm. Of the 150 patients enrolled in the study, 75 were randomly assigned to the control group and were assigned 75 to the intervention arm using block randomization. Patients provided the names of all physicians to whom they would want their laboratory results sent, and standard laboratory reports were sent to all of these physicians.

Standard care (control)

Patients in the control group received usual diabetes healthcare advice provided by their physician during the study period. Other than the initial interview by a CDE, no additional diabetes educational materials were provided (Table 1).

Intervention

Each patient in the intervention group received a computer-generated customized report presented as an 11" × 17" laminated color poster backed with magnets, with a bulleted list of personalized goals and recommended steps for achieving the goals (Fig. 1). The individual's report was generated from a Microsoft Access–based decision support system that collected patient information from the enrollment questionnaire and matched it against a knowledge base of established diabetes, cardiovascular, nutrition, and exercise guidelines.

There was no subjective interpretation from the personal interview. The questionnaire asked participants to provide the names of family members, pets, or friends who exercise, cook, or share time with the participant, and these names were included in the personalized reports. The posters included discussion points for patients to mention to their physicians. For example, for a patient who was treated with a submaximal dose of a glucose-lowering medication but had not achieved their HbA_{1c} goal, their action plan would include a recommendation to talk to their physician about optimizing their glucose-lowering medication. The report included both the generic and trade names of medications. Patients also received a personalized wallet card (Fig. 2) that included their baseline HbA_{1c}, lipid, and blood pressure status, with room to document subsequent values. For the duration of the study, each patient was sent one postcard (Fig. 3) per month that emphasized the relation between HbA_{1c} and diabetes-related complications and provided an action step for lowering HbA_{1c} (Table 1).

After receipt of the poster and personalized wallet card, intervention patients received one phone call from a health educator to discuss their personalized poster. This structured phone call lasted no more than 10 min and strictly focused discussion on the patient's report. There were no other educational, nutritional, or exercise interventions provided. The health educator told patients to discuss issues and questions regarding medication and dosing with their primary physician.

In addition to a traditional laboratory report form, physicians whose patients were randomized to the intervention received a unique color report (Fig. 1) that was similar to the poster that their patient received but was designed for the patient's medical record. In addition to a graphic display of their HbA_{1c}, both the patient's and physician's personalized report included information on the patient's blood pressure, lipid, and microalbumin status; the date for the patient's next dilated retinal examination; and bulleted suggestions on management of their patient based on the following: ADA's 1998 Clinical Practice Recommendations, the Kaiser Permanente of Mid-Atlantic Region Clinical Guidelines to the Management of Diabetes, the National Cholesterol Education Program, Healthy People 2000, the National Institutes of Health Consensus Statement on Physical Activity and Cardiovascular Health, and the Departments of Agriculture and Health and Human Services' Dietary Guidelines for Americans (29–34). The tailored suggestions were tested among patients and physicians before the study for their appropriateness.

Follow-up

At 6 months after enrollment, all patients received a follow-up letter and questionnaire. Follow-up appointments occurred at the MedStar Clinical Research Center. At the close of the study, all patients and their physicians received a letter with their baseline and follow-up results.

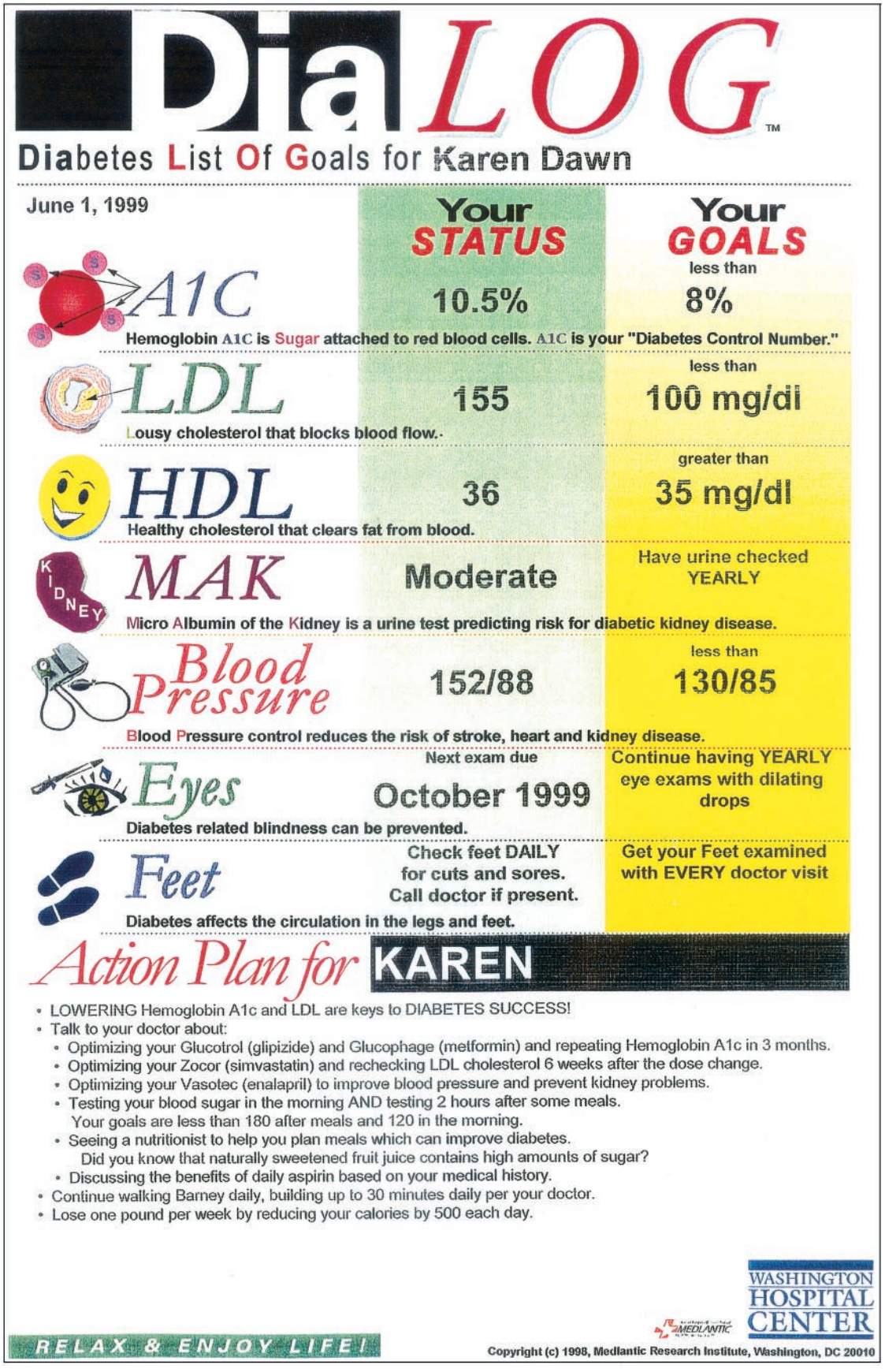

Figure 1—*Personalized 11" × 17" poster, laminated and backed with magnets for patients to place on their refrigerator.*

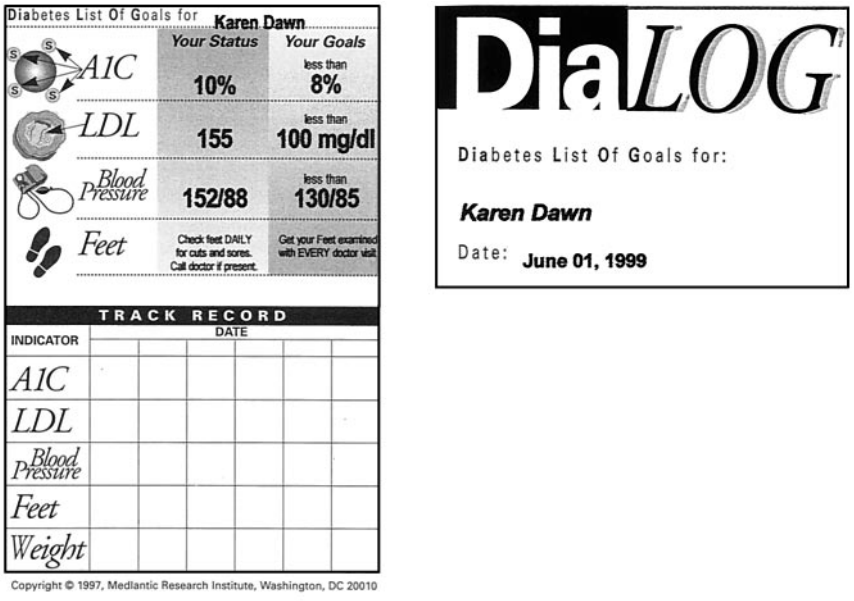

Figure 2—*Personalized wallet card identifying baseline status, with room for documenting follow-up HbA_{1c} tests and blood pressure status.*

Laboratory measurements

The Penn Medical Laboratory (Washington, DC) performed all HbA_{1c} and cholesterol profiles in serum collected after a 12-h fast. Direct LDL and HDL cholesterol levels were measured enzymatically on a Hitachi 717 autoanalyzer using reagents supplied by Roche Diagnostics (Indianapolis, IN). The laboratory used Abel-Kendall analyzed serum, purchased from Northwest Lipid Research Laboratory (Seattle, WA), as the calibrator. Controls included those supplied by Roche and Northwest Lipid Research Center (NWLRC). The laboratory participates in the NWLRC lipid quality assurance program (Cholesterol Standardization Certification). LDL cholesterol was measured directly in fresh plasma using reagents from Sigma Diagnostics (St. Louis, MO). Urine microalbumin testing was performed using Micral urine test strips provided by Roche.

Statistical methods

Power calculations. We anticipated a 10% change in HbA_{1c} levels (~0.8% absolute reduction) during the 6-month study period among intervention patients, assuming equal variation between groups (estimated SD 1.9) (35). A sample size of 63 per group was needed to reach statistical significance, using a Student's *t* test. We assumed a dropout rate of 10% from this urban, minority population during the 6-month study period, yield-

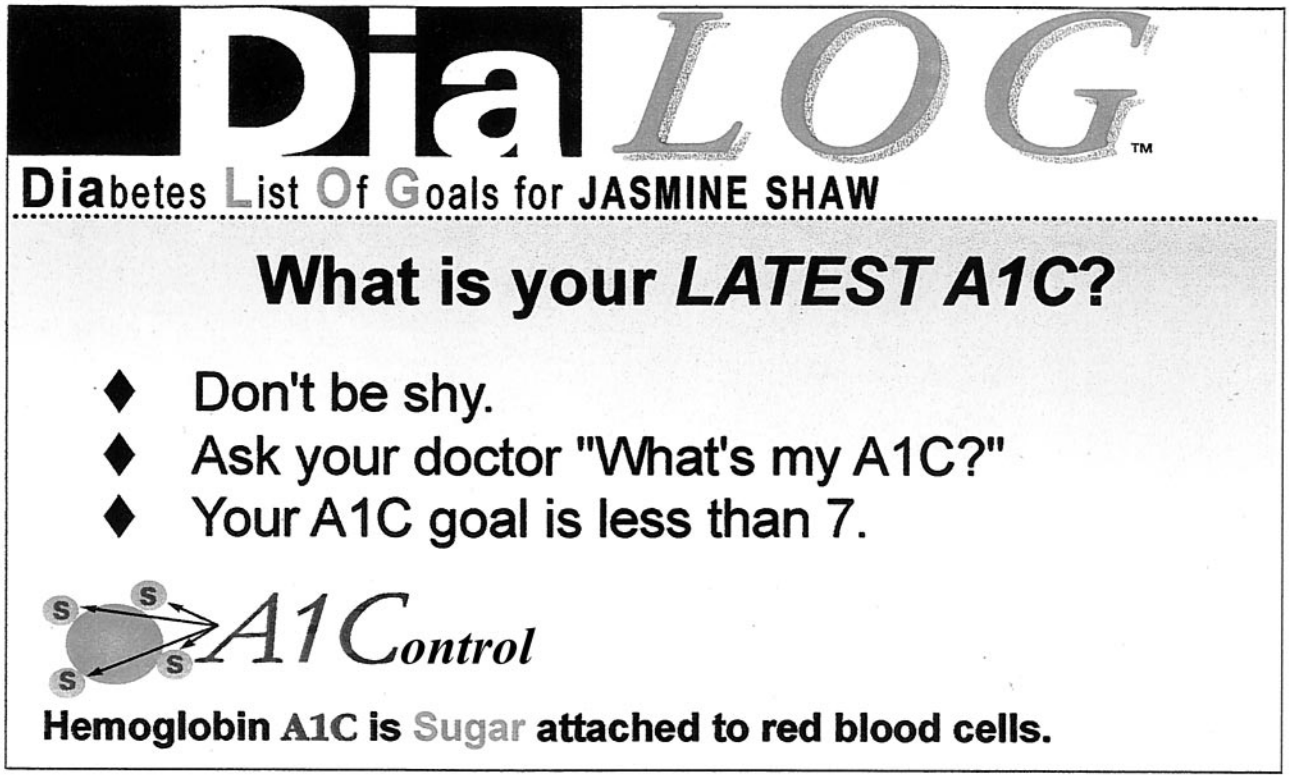

Figure 3—*One of five monthly postcards sent to patients in the intervention group. The postcards emphasized the importance of achieving HbA_{1c} goals and urged patients to receive follow-up cholesterol testing.*

Table 2—*Patient characteristics at baseline*

Variable	Control	Intervention	*P**
n	64	64	
Male sex (%)	30	35	0.71
African-American (%)	83	89	0.32
Age (years)	60	57	0.25
Height (in)†	66	66	0.97
Weight (lb)†	197	197	0.62
Systolic BP (mmHg)†	143	142	0.85
Diastolic BP (mmHg)†	83	83	0.80
Education (% no college)	44	47	0.62
Duration of diabetes (years)‡	3	5.5	0.10
HDL cholesterol (mg/dl)†	41	42	0.57
Microalbuminuria (% with 30–300 μg)	61	58	0.72
LDL cholesterol (mg/dl)†	116	115	0.98
HbA_{1c} (%)	8.39 ± 2.03	8.85 ± 2.48	0.25
Home glucose monitoring (%)	89	87	0.88
Heard of "A-One-C" test (%)	52	42	0.47

Data are means and means ± SD, unless otherwise indicated. **P* values <0.05 were considered significant; †median with upper and lower bound for median; ‡Fisher's Exact (2-tailed); all others report 95% CI about the mean. BP, blood pressure.

ing a total recruitment size of 146 to complete the study (37). These estimates were conservative because they assumed an analysis would be univariate. The analysis used a t^2 test (a multivariate *t* test). The experimental-wise error rate was set at 0.05 (the test-based α was 0.025), and the type II error rate was set at 0.2.

Analysis of results. The major outcome variable was HbA_{1c}. Differences between pre- and posttreatment intervention periods and the control group at baseline and follow-up were assessed using parametric (Student's *t* tests), nonparametric (median tests), and contingency table analyses (Fisher's exact tests) to detect the difference in demographics and laboratory assignment variables between the patient study groups. The changes observed within each cohort were evaluated for significant differences between the pre- and postintervention periods using a two-tailed paired *t* test. The significance of the difference between the treatment and control groups was evaluated by repeated measures of analysis of variance that tested for changes between the two groups from the pre- to postintervention periods while controlling for the different baseline values on the outcomes of interest. A *P* value <0.05 was considered significant.

RESULTS — Of the randomized patients, 85.3% completed the study and were evaluated in the final analysis. There was one death in the control group that was attributed to cardiovascular disease. Three patients in the control group developed chronic debilitating syndromes (e.g., cancer) and were dropped from the study, two lab specimens were lost, and five patients declined follow-up after initial enrollment.

Among the intervention group, there was one death, two lost laboratory specimens, and seven patients who declined follow-up. One patient developed a chronic debilitating illness requiring chronic corticosteroid therapy and was dropped from the study. We report the data on the 128 remaining patients in the intervention and control group, all of whom completed the final questionnaire and returned for follow-up HbA_{1c} and cholesterol testing.

There were no significant differences between the intervention and control groups with respect to baseline age, sex, education level, race, baseline cholesterol levels, and comorbidities (Table 2). Patients were similar with respect to baseline HbA_{1c} and LDL and HDL cholesterol. More than half of the patients in each group reported a history of hypertension, and 75% (49 control and 45 intervention patients) had a baseline HbA_{1c} ≥7.0%.

At the 6-month follow-up, there were no significant differences in outcomes within or between groups with respect to weight, systolic or diastolic blood pressure, or lipids (Table 3). There was also no difference between the control and intervention groups with respect to the percentage of patients in each group who experienced a decline in HbA_{1c} (63 vs. 69%; $P = 0.87$).

At the study close, the intervention patients had a significant reduction in HbA_{1c} compared with control subjects (Table 4). Among patients with a baseline HbA_{1c} ≥7.0%, there was an 8.6% (0.77% absolute) reduction in HbA_{1c} among control subjects and a 17.0% (1.69% absolute) decline in the intervention group ($P = 0.032$).

In both the control and intervention groups, the most sizable and significant reductions in HbA_{1c} were noted among the subgroup of patients who lowered their HbA_{1c} during the study period and were classified as responders. Responders in the control group experienced a decline of 13.3% (1.15% absolute) as compared with intervention responders, who had a decline of 24.2% (a 2.26% absolute reduction; $P = 0.0048$) during the study period. Altogether, 61% of responders who were not at the goal at baseline in the intervention group and 38% of control patients achieved an HbA_{1c} of ≤7% ($P = 0.05$) by study end.

Table 3—*Changes from baseline at follow-up*

Variable	Control Δ from baseline	Intervention Δ from baseline
n	64	64
Weight (lb)	+1.0	+1.54
Systolic BP (mmHg)	−4	−4
Diastolic BP (mmHg)	−5	−4
HDL cholesterol (mg/dl)	+3	+3
LDL cholesterol (mg/dl)	−7	−5
Heard of "A-One-C" test (%)	−5.1	+14.3

BP, blood pressure.

Table 4—*Changes in HbA_{1c} from baseline*

HbA_{1c}	Control	Intervention
n	64	64
Baseline (%)	8.39 ± 2.03	8.85 ± 2.48
End of study (%)	7.79 ± 1.91	7.78 ± 2.22
Change from baseline (%)	−0.6 ($P > 0.05$)	−1.08 ($P = 0.013$)*

Data are means ± SD. **P* value within group comparison.

There were no significant changes in weight during the study period seen in either the control or intervention patients (Table 3). The intervention was equally effective among patients who had only grade school or high school education compared with those with a college education. At the study close, 77% of all patients in the intervention group reported that their poster remained displayed on their refrigerator. Patients in the intervention group reported greater changes in their diabetes medications; they were also more likely to talk to their physicians about checking their HbA_{1c} level and were knowledgeable of the HbA_{1c} test, but these self-reported outcomes trended toward, but did not achieve, statistical significance.

CONCLUSIONS — Putting prevention into practice is one of the three major goals of Healthy People 2000, the national health promotion and disease prevention objectives of the U.S. Department of Health and Human Services (30). Based on the simplistic hypothesis that knowing ones own glycemic status and goals could potentially improve performance, the study set forth to put prevention into practice among patients with diabetes by developing and testing the impact of computer-generated personalized empowerment tools that were designed to lower HbA_{1c} concentrations and that required no effort on the part of the health care provider.

Similar to many other studies, we found that diabetes educational interventions do not result in a decline in HbA_{1c} among all patients (19). After an ADA-recognized education course, >60% of the patients experienced a reduction of their HbA_{1c} level during the study period, yet even greater improvement was seen among patients in the intervention group. We attribute these findings to the constant visual reminder to patients and their families of their diabetes status and goals. We are particularly impressed by the ability of the intervention to lower HbA_{1c} in a predominately minority population, demonstrating the cultural sensitivity of the intervention. The visual nature of the intervention may also have contributed to the success of the intervention in a population with less than a college education.

The Industrial Revolution taught that performance and production among assembly line workers were enhanced when individuals knew their goals and were given feedback on their own production rate (37). These same theories of enhancing task performance by involving patients directly with their diabetes goals were used in this study. Unlike providing generalized knowledge on the subject of diabetes, we allowed patients and their families to have a benchmark of their personal diabetes status and their goal.

The poster was not thrown away or filed away in a drawer, and most of the patients kept the poster up on their refrigerator for the duration of the study. All patients were recruited from those who received diabetes education during a 3-month period before recruitment, and thus our patient population was sufficiently motivated to voluntarily attend an ADA-recognized self-management program, which may explain why the majority of patients in both groups experienced a reduction in HbA_{1c}.

It was the objective of the researchers to help patients feel that good health is within their ability to achieve, i.e., to strengthen their internal locus of control (38,39). We embraced the concepts of Dr. Elliott P. Joslin that "the person with diabetes who knows the most about their disease, lives the longest" (40). The investigators believe that the greatest impact resulted from a patient seeing his or her own diabetes status and goal.

The software algorithm uses laboratory data and patient data derived from a short questionnaire that can be self-administered. The investigators have developed a system to make these tools available to physician practices and managed care populations; this system may serve as an adjunct to traditional diabetes self-management training, with potential HbA_{1c} lowering comparable to that of oral agents.

Although we demonstrated that personalized empowerment tools could potentially have a significant impact on short-term HbA_{1c} outcomes, further study is necessary to determine the long-term implications of personalized empowerment tools, such as the ones we designed on diabetes-related outcomes. As we develop a strategic health plan for the 21st century, the critical research that identifies the genetic, physiological, and environmental determinants of disease must also be accompanied by clinical research that evaluates how scientific advances can best be translated into practical steps that patients can use to improve their health.

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